

REMARKS

Applicant has carefully reviewed the Office Action of November 12, 2009 prior to preparing this response. Applicant respectfully traverses (and does not concede) all objections, rejections, and adverse assertions made by the Examiner. With this paper, claims 19, 24-25, 28, 32-34, and 37 have been amended. Support for the amendments is found in the specification, claims, and drawings as originally filed. No new matter has been added. Claims 19-22, 24-26, 28-35, 37 and 38 remain pending. Favorable consideration of the above amendments and the following remarks is respectfully requested.

Drawings

Applicant wishes to thank the Examiner for indicating the objection to the drawings made in the Office Action of November 21, 2008 (the Examiner indicated November 21, 2009, but this is believed to be a typographical error) have been withdrawn.

On page 2 of the Office Action, the drawings have been objected to under 37 CFR 1.83(a). The Examiner asserts the distal end and proximal end of the tubular shaft must be shown or the feature canceled from the claims. While Applicant does not concede the correctness of the objection, in the interest of furthering prosecution, the claims have been amended to recite a proximal junction (shown at reference numeral 184) and a distal junction (shown at reference numeral 186). No new matter has been added. Reconsideration and withdrawal of the objection are respectfully requested.

Claim Rejections under 35 U.S.C. §112

On page 3 of the Office Action, claims 19-22, 24-26, 28-35, and 37-38 have been rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. In particular the Examiner asserts, "[t]he claims recite a polymer layer, which is disposed both under and over the braid. It is unclear whether there is a single polymer coating that covers both the braid and the nitinol tubing, or whether there are two separate coatings, which are distinct from each other." While Applicant does not concede the correctness of the rejection, the claims have been amended for clarification. For example, claim 19 has been

amended to recite "at least a distal portion of the braid is disposed over and contacting a first polymer layer" and "a second polymer layer disposed over the tubular shaft and the braid."

The Examiner further asserts, "the claims recite 'a braid attached to the distal end of the tubular shaft', which in the specification is described as junction 186 (page 5 lines 15-17). This junction is shown inconsistently between figure 2A and 2B." At page 2, lines 21-22 of the parent specification Figure 2A is described as "a side-elevational view of a catheter shaft constructed in accordance with an embodiment of the invention with portions of the catheter shaft cut away." Emphasis added. The view in Figure 2A does not preclude the braid 170 from extending proximal of the distal junction 186, but merely does not cut away that portion of the catheter shaft. Moreover, claim 19, as amended, recites, "the braid is disposed over the distal junction of the tubular shaft such that a portion of the braid is located proximal of the distal junction of the tubular shaft." Applicant respectfully asserts the claims are consistent with drawings. Reconsideration and withdrawal of the rejection are respectfully requested.

Claim Rejections under 35 U.S.C. §103

On page 4 of the Office Action, claims 19-22, 24, 26, 28-33, 35, 37 and 38 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Lundquist (U.S. Patent No. 5,228,441) in view of Webster, Jr. (U.S. Patent No. 5,057,092), hereinafter "Webster" and Samson (U.S. Patent No. 5,702,373). Applicant respectfully traverses the rejection.

Independent claim 19 recites in part, "the distal shaft section including a braid attached to the distal end of the tubular shaft and at least a distal portion of the braid is disposed over and contacting a first polymer layer." Independent claim 28 recites in part, "a polymer layer disposed over the tubular member and the braid and extending distally to a distal end of the distal shaft portion." Independent claim 37 has been amended to recite similar limitations. As can be seen, the presence of the inner polymer layer and the outer polymer layer create a smooth inner surface and smooth outer surface. As acknowledged by the Examiner Lundquist does not appear to teach or suggest such properties. The Examiner relies on Webster and Samson as disclosing these limitations.

In formulating the rejection, the Examiner asserts:

Webster teaches a catheter with a braided layer (24) that extends to the distal end, and is disposed over a polymer layer (22) and that has a [sic] outer polymer layer (30) covering the tubular shaft and the braid.

Samson teaches a similar catheter where the braided layer overlies the distal end of a metallic tubular member (see figure 11).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the torqueable and deflectable catheter of Lundquist with the polymer layers of Webster and Samson to produce a catheter section that is very flexible but highly kink resistant (Samson, abstract).

Applicant respectfully disagrees. The Supreme Court in *KSR Int'l Co. v. Teleflex Inc.* quotes *In re Kahn*, 441 F. 3d 977, 988 (CA Fed. 2006), “[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness”. Emphasis added; see page 14 of the April 30, 2007 Decision. The Court further stated, “a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art”. See page 14 of the April 30, 2007 Decision. Applicant respectfully asserts the Examiner has failed to provide an articulated reasoning with rational underpinning to support the conclusion of obviousness.

Lundquist appears to disclose a catheter having a high torque capability. The catheter of Lundquist appears to include a torque tube 31 extending from the proximal end to near the distal extremity 24. Lundquist further appears to disclose a thin walled shrink tubing 46 is disposed over the outer surface of the torque tube. Lundquist disclose at column 4, lines 51-58:

The shrink tubing 46 is very flexible and permits desired flexing of the torque tube 31 but prevents undue bending or stress in the material of the side wall in any one slot and thereby prevents the placement of a permanent strain in any portion of the tube. In other words, the tubing 46 prevents bending or flexing of the torque tube beyond the point from which it will not yieldably return to its original configuration.

Lundquist appears to disclose the shrink tubing provides kink resistance. Lundquist further appears to disclose a braided tubular member 54 extending from the shrink tubing 46 to a point proximal the distal end. A distal portion of the outer surface of the tubular member appears to form the outer surface of the catheter for at least some length before the distal end of the tubular member is bonded to a soft plastic tubing 61. Lundquist further appear to disclose soft plastic

tubing 61 extends from the distal end of the braid to the distal end of the catheter shaft where an electrode 28 is positioned.

The Examiner appears to be asserting that one of ordinary skill in the art would modify the distal end of Lundquist such that the braided tubular member 54 extends to the distal end and to provide a polymer layer on top of and below the tubular member. It appears the proposed modification would not only increase the diameter of the device of Lundquist, but also may inhibit the functionality of the distal electrode 58. Insofar as it may not be able to fit where it otherwise could have fit without the design change, the proposed modification may indeed render the prior art device unsatisfactory for its intended purpose. MPEP 2143.01 V states, "If proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984)."

Therefore, for at least the reasons set forth above, none of Lundquist, Webster, and/or Samson, taken alone or in combination, appears to teach or suggest each and every element of independent claims 19, 28 or 37. Furthermore, there appears to be no motivation, suggestion or other reason for one of ordinary skill in the art to modify Lundquist to arrive the device as claimed. Reconsideration and withdrawal of the rejection are respectfully requested. For similar reasons and others, Applicant submits that claims 20-22, 24, 26, 29-33, 35 and 38 are also in condition for allowance as they depend from one of claims 19, 28 and 37 and they add significant limitations to further distinguish them from the prior art.

Claims 25 and 34 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Lundquist (U.S. Patent No. 5,228,441) in view of Webster (U.S. Patent No. 5,057,092), and Samson (U.S. Patent No. 5,702,373), and further in view of Schwartz et al. (U.S. Patent No. 5,437,288). Applicant respectfully traverses this rejection.

Claim 25 depends from claim 19 and claim 34 depends from claim 28. For at least the reasons stated above, the combination of Lundquist, Webster, and Samson fails to teach each and every limitation of claims 19 and 28. Schwartz et al. do not appear remedy the shortcomings of Lundquist, Webster, and Samson. Thus, even if one were to combine Lundquist, Webster, Samson, and Schwartz et al., one would not arrive at the device as claimed. Furthermore, there

appears to be no motivation, suggestion or other reason for one of ordinary skill in the art to modify Lundquist and/or Schwartz et al. to achieve the device as claimed.

Therefore, because claims 19 and 28 are believed to be in condition for allowance, Applicant submits that claims 25 and 34, which depend from claims 19 and 28, respectively and which add further limitations, are believed to be in condition for allowance. Withdrawal of the rejection is respectfully requested.

Conclusion

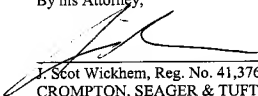
Reconsideration and further examination are respectfully requested. It is respectfully submitted that all pending claims are now in condition for allowance. Issuance of a Notice of Allowance in due course is requested. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,

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By his Attorney,

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